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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/779,315	02/17/2004	Steven Horan	A9038	5247

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EXAMINER	
MCEVOY, THOMAS M	

ART UNIT	PAPER NUMBER
3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/779,315	HORAN ET AL.	
	Examiner	Art Unit	
	THOMAS MCEVOY	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,6,9-17,20-22,24,25,36-39,52-56,58,59 and 69-88* is/are pending in the application.

4a) Of the above claim(s) *69-88* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,6,9-17,20-22,24,25,36-39,52-56,58 and 59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 3, 6, 9-11, 24, 25, 52, 53, 58 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leschinsky (US 6,827,730) in view of Park et al. (US 6,645,239) and Lenker et al. (US 6,126,685).

Regarding claim 1, Leschinsky discloses a delivery system for delivery and deployment of a self expanding stent to a desired vascular location of a patient, the system comprising: a stent 30, the stent having a proximal end and a distal end; a catheter shaft 10 having a proximal end and a distal end, the distal end of the shaft defining a reception space for receiving the stent (Figure 4), the stent having a reduced diameter delivery configuration (Figure 4 vs. Figure 5); an inner core 40 having a proximal end and a distal end and a length, the stent disposed radially about the distal end of the inner core (Figure 3); an outer core 20, the outer core having a proximal end and a distal end and a length, the outer core disposed radially about the inner core (Figure 3), wherein the length of the outer core is less than the length of the inner core (Figure 4), the distal end of the outer core is capable of engaging with the proximal end of the stent. Leschinsky fails to disclose that the outer core is affixed to the inner core.

Leschinsky does not disclose any function or criticality to the axially moving relationship between the inner core and the outer core. The inventive concept that Leschinsky is directed to is the relative diameters of the stabiliser and distal end of the catheter shaft; not the method of stent deployment. Park et al. disclose a stent delivery system where, like Leschinsky, an outer core is disposed over an inner core to create a stent reception space. Park et al. teach a method of deploying a stent by pushing it out of a catheter shaft by an inner and outer core which results in easy and precise deployment of the stent (col. 2, lines 20-35). Park et al. disclose the outer core being affixed to the inner core (col. 3, lines 43-46) so that a stent can be pushed and pulled into the catheter with minimal handle motions while maintaining the length of the stent reception space (although this reason for the fixed attachment is not explicitly disclosed, it is more than apparent from the overall disclosure). It would have been obvious to one of ordinary skill in the art in view of Park et al. to have fixed the outer core of Leschinsky to the inner core (and possibly attach the stent by thread to the inner core) so that a stent can be easily and precisely pushed out and pulled back in with minimal handle motions; noting that Park et al. discourage moving the inner core proximally to pull the stent into the catheter shaft. The skilled artisan would recognize that without this fixed attachment, the stent reception space would be affected by moving the inner core and outer core separately; possibly creating a larger, unsupported reception space during deployment and possibly affecting ability of the catheter shaft to be easily slid back over the inner core if the stent needs to be pulled back into the catheter. It would have been obvious to one of ordinary skill in the art in view of Leschinsky alone or in combination

with Park et al. to have provided an operator handle for movement of the catheter shaft relative to the inner core and the outer core to deploy the self expanding stent since the catheter shaft must be manually moved in both references. Leschinsky discloses a stabiliser component 57 having a distal end and a proximal end, the distal end being disposed proximally to the stent (Figure 5). Leschinsky fails to disclose that the inner core and outer core are fixed to the stabiliser component. Lenker et al. teach that an catheter core should be attached to a stabiliser in order to hold the core stationary while a catheter shaft is moved (evident from Figures 3-6). It would have been obvious to one of ordinary skill in the art in view of Lenker et al. to have fixed the inner and outer cores of the Leschinsky device (as modified by Park et al.) to the stabiliser in order to hold the cores stationary while the catheter shaft is moved. Regarding claim 3, member 50 of Leschinsky could be considered as part of the inner core. Regarding claims 6 and 24, Leschinsky does not disclose the materials for the delivery system; leaving the reader to seek out suitable materials in the prior art. Lenker et al. teach that an inner core of similar design and function can be made from a composite (column 8, lines 29-44). It would have been obvious to one of ordinary skill in the art to have constructed the inner core of Leschinsky from a composite material because Lenker et al. teach this a suitable material for a similarly functioning structure. Leschinsky already discloses that distal end of the catheter shaft has a low friction inner surface (low enough to allow sliding engagement with the stent since the stent expands upon retraction of the catheter shaft). Regarding claim 9, Leschinsky discloses that the catheter shaft comprises a distal sheath portion 42 and a proximal shaft portion 43, the diameter of the

proximal shaft portion being smaller than the diameter of the distal sheath portion (Figure 3). Regarding claim 10, the stabiliser component of Leschinsky is disposed over the smaller diameter proximal shaft (Figure 4). Regarding claim 11, the stabiliser of Leschinsky comprises a tube and the diameter of the stabiliser tube is not greater than the diameter of the distal sheath of the catheter shaft (Figure 4 and elsewhere). Regarding claim 25, Leschinsky in view of Park et al. and Lenker et al. disclose the composite shaft as described above. It would have been further obvious to one of ordinary skill in the art to have made the composite shaft with a additional reinforcement as claimed because Lenker et al. teach that this will enhance strength, flexibility and toughness (column 8, lines 29 to 38). Regarding claims 52 and 53, the inner core of Leschinsky defines a guidewire lumen with a guidewire 58 along the length thereof (Figure 4). Regarding claims 58 and 59, both Leschinsky and Lenker et al. disclose that the stabiliser has an open proximal end which would therefore allow the backflow of blood. Leschinsky further discloses that the stabiliser extends substantially the length of the catheter shaft (Figure 4).

3. Claims 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leschinsky (US 6,827,730) in view of Park et al. (US 6,645,239) and Lenker et al. (US 6,126,685), as applied to claim 9 above, and further in view of Healy et al. (EP 1095634).

Regarding claims 12-17, Leschinsky in view of Park et al. and Lenker et al. disclose the delivery system as described above. Leschinsky in view of Park et al. and Lenker et al. does not teach that the catheter shaft has a guidewire exit port which is

located proximally of the distal end of the catheter shaft; wherein the guidewire exit port is located proximally of the stent and delivery sheath; wherein he guidewire exit port is located at a transition between the distal sheath and the reduced diameter proximal shaft portion; wherein the guidewire exit port is located distally of the stabiliser component; wherein the guidewire exit port is configured to exit along an axis that is substantially parallel to a longitudinal axis of the distal sheath. Healy et al. who disclose a rapid exchange catheter configuration where the guidewire exit port is at an intermediate, transition section 46 (Figure 2) of the catheter shaft, just prior to the delivery sheath 28/30 (Figure 2) and distally of the stabilizer (column 10, lines 52-55) where it exits in a line that is substantially parallel to a longitudinal axis of the distal sheath (Figure 1 at 44). This design addresses the challenge of maintaining alignment of the inner and outer guidewire ports (column 5 – lines 10-11). It would be obvious to one of ordinary skill in the art, to combine the invention of Lenker et al. in view of Leschinsky with the guidewire port configuration of Healy et al. in order to have the operational advantages of a rapid exchange catheter and minimize misalignment of the guidewire exit port during sheath retraction.

4. Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leschinsky (US 6,827,730) in view of Park et al. (US 6,645,239) and Lenker et al. (US 6,126,685), and further in view of Blaeser et al. (US 6,168,617).

Regarding claims 20-22, Leschinsky in view of Park et al. and Lenker et al. discloses a delivery system wherein the inner core comprises a large diameter distal segment and a reduced diameter proximal segment (as described above for claim 3).

Leschinsky in view of Park et al. and Lenker et al. does not disclose a transition segment between the distal and proximal segments; wherein the transition segment is proximal of the abutment region; wherein the transition segment is distal of a guidewire exit port. Blaeser et al. disclose a catheter with an inner core 18 (Figure 2) having a reduced diameter transition portion extending through the stent (Figure 2) in order to reduce the overall diameter of the catheter at the distal end to facilitate ease of movement through arteries and lesion sites (column 2, lines 46 to 59). It would be obvious to one of ordinary skill in the art to have reduced the diameter of the inner core further, in view of Blaeser et al., at least through the stent engaging section which includes abutments (as described for claim 2), in order to reduce the diameter of the distal end of the catheter which would facilitate its movement through arteries and lesion sites.

5. Claims 36, 54 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leschinsky (US 6,827,730) in view of Park et al. (US 6,645,239) and Lenker et al. (US 6,126,685), and further in view of Burns (US 5,032,113).

Regarding claims 36, 54 and 55, Leschinsky in view of Park et al. and Lenker et al. disclose a system as described above. Leschinsky in view of Park et al. and Lenker et al. does not disclose that the system comprises a procedural guidewire and the guidewire is fixed or fixable to the stabiliser component; wherein the system includes a lock for the guidewire; wherein the lock is located proximal of the handle. Burns discloses a manifold 21 containing Touhy Borst fittings to provide a hermetic seal for a guidewire 22 and to lock the relative position of the guidewire and catheter tube (Figure

1A; column 4, lines 37-40). It would be obvious to one or ordinary skill in the art, in view of Burns, to use a Touhy Borst fitting in combination with a manifold to hermetically seal a guidewire to the catheter thereby fixing it, indirectly, to the stabiliser. It would also be an obvious design choice to one of ordinary skill in the art in view of Lenker et al. to have connected the stabiliser to an introducer sheath or guide catheter via a Touhy Borst fitting, in order to anchor the stabiliser to the introducer sheath or guide catheter as taught by Lenker et al. (column 7, line 66 to column 8, line 6).

6. Claims 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leschinsky (US 6,827,730) in view of Park et al. (US 6,645,239) and Lenker et al. (US 6,126,685), and further in view of Lenker et al. (US 5,683,451).

Regarding claims 37-39, Leschinsky in view of Park et al. and Lenker et al. '685 discloses the system as described above. Leschinsky in view of Park et al. and Lenker et al. '685 do not disclose that the stabiliser component is length adjustable; wherein the stabiliser component comprises at least two parts which are movable relative to one another. Lenker et al. '451 disclose that a stabiliser 38 (Figure 2) can contain a slidable piece or slider 50 (Figure 2) which allows for length adjustment of the stabiliser so that it can be fit into an external control device (evident from Figure 33). It would be obvious to one of ordinary skill in the art and to have provided the slider of Lenker et al. '451 so that an external control device can be used.

7. Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Leschinsky (US 6,827,730) in view of Park et al. (US 6,645,239) and Lenker et al. (US 6,126,685), and further in view of Harvey et al. (US 4,607,868).

Regarding claim 56, Leschinsky in view of Park et al. and Lenker et al. discloses a system as described above wherein the stabiliser component comprises a tubular element (Figure 4 of Leschinsky or Figure 6 of Lenker et al.). Leschinsky in view of Park et al. and Lenker et al. does not disclose that the tubular element has a tapered distal end. Harvey et al. teach that it is well known in the medical art to make tube connections by tapering the end of a tube to fit into a leur adapter (column 1; lines 27 to 30). It would be obvious to one of ordinary skill in the art to have connected the stabiliser of Lenker et al. to an introducer sheath (column 4, lines 37 to 39), via a leur adapter and tapered ends as taught by Harvey et al.

Response to Arguments

8. Applicant's arguments filed May 14th 2009 have been fully considered but are moot in view of the new grounds of rejection.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas Mcevoy whose telephone number is (571) 270-5034. The examiner can normally be reached on M-F, 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent

11. Application Information Retrieval (4PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thomas Mcevoy/
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
10/08/09